IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 13 CASES LISTED IN EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE GENERAL OPINIONS AND TESTIMONY OF STACEY WALLACH, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") move to exclude certain general testimony and opinions of Plaintiffs' expert, Stacey Wallach, M.D. As an initial matter, Dr. Wallach has not been properly designated as a general expert in any Wave 13 case; no plaintiffs have served a general causation report, and no plaintiffs have explicitly designated her as a general expert. *See* Ex. B, Wave 13 Pls.' General Expert Witness Disclosure. Plaintiffs Naomi Larson and Mark Larson disclosed Dr. Wallach as an expert urogynecologist, but did not specifically designate her as either case-specific or general. *See* Ex. C, Larson Pls.' Rule 26 Expert Disclosures. The Larson Plaintiffs served Ethicon with Dr. Wallach's case-specific report, which also includes a number of general opinions. *See generally* Ex. D, Case-Specific Expert Report of Stacey Wallach, M.D. ["Case-Specific Report"]. While this is insufficient to designate Dr. Wallach as a general expert, Ethicon responds to her general opinions through an MDL filing in recognition of this Court's repeated instruction that challenges to general opinions should be filed in the MDL.

As set forth below, Dr. Wallach's proffered general expert testimony is unreliable, irrelevant, unhelpful, and otherwise inadmissible under the standards set forth in Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny.

To the extent this Court does not exclude Dr. Wallach's general causation opinions entirely on the basis that she has not been properly designated as a general causation expert, for the reasons below, the Court should preclude her from offering the following expert testimony and opinion: (1) opinions regarding corporate knowledge and conduct, as well as opinions containing legal conclusions, standards, and terms of art; (2) opinions regarding the adequacy of Ethicon's product warnings (including opinions about the informed consent process); (3) opinions regarding allegedly safer treatments for pelvic organ prolapse; and (4) opinions on the competence of other physicians.

BACKGROUND

1. The Larson Plaintiffs have disclosed Dr. Wallach as an expert urogynecologist, without specifically designating her as a case-specific expert, a general expert, or both. *See generally* Ex. D, Case-Specific Report; Ex. C, Larson Pls.' Rule 26 Disclosure. Dr. Wallach has not been disclosed as a general causation expert in any other Wave 13 case. *See* Ex. B, Wave 13 Pls.' General Expert Witness Disclosure.

2. Ethicon has been served with a case-specific report for Dr. Wallach, but no general report. *See* Ex. D, Case-Specific Report. However, despite her apparent designation as a specific causation expert, Dr. Wallach's Case-Specific Report contains several pages of general causation opinions on Ethicon's Prolift device. *See generally* Ex. D, Case-Specific Report.

3. Dr. Wallach opines that "Ethicon failed to adequately warn physicians and patients about known problems with their Prolift products,]" and that the "design of the Prolift products is defective." *Id.* at 24–26.

4. Dr. Wallach opines that "safer alternatives—including nonsurgical and surgical treatment options could have been chosen for Ms. Larson." *Id.* She opines that the following "safer surgical interventions[]" that "could have been chosen for her[]": native tissue prolapse repair, the use of biologic grafts instead of synthetic mesh, or an abdominal sacrocolpopexy. *Id.* at 31.

5. Dr. Wallach offers several opinions bearing on the competence of other physicians, including that "[i]n the hands of many gynecological and urological surgeons, the blind passage of the metal trocars done during the implantation is unreasonably dangerous," and that "[e]ven to remove portions of the [Prolift] necessitates invasive surgery that few surgeons are qualified to perform." Ex. D, Case-Specific Report at 26.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1–3 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. The Court Should Exclude Dr. Wallach's General Causation Opinions Offered in Her Case-Specific Report.

The Larson Plaintiffs have disclosed Dr. Wallach as a case-specific expert urogynecologist. *See generally* Ex. D, Case-Specific Report. However, as noted, the Larson Plaintiffs' did not specifically designate Dr. Wallach as a case-specific expert in their expert disclosures. Ex. C, Larson Pls.' Rule 26 Disclosures. Neither the Larson Plaintiffs nor any other Wave 13 Plaintiffs have served Ethicon with a general report produced by Dr. Wallach. *See* Ex. B, Wave 13 Pls.' General Expert Witness Disclosure.

However, although she has not been disclosed as a general causation expert, Dr. Wallach's Case-Specific Report contains several pages of general causation opinions, including opinions regarding complications not experienced by Ms. Larson. *See, e.g.* Ex. D, Case-Specific Report at 3, 24–27. Because she has not been properly disclosed as a general expert, this Court should exclude the general causation opinions set forth in Dr. Wallach's Case-Specific Report.

A. Dr. Wallach has not been designated as a general causation expert.

This Court has recognized that it is inappropriate for witnesses who have not been disclosed as general causation experts to offer general causation opinions, and limited their opinions accordingly.

In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. 2:12-cv-00737, 2016 WL 7242550, at *2 (S.D. W. Va. Dec. 14, 2016) (noting plaintiff's failure to disclose the witness as a general causation expert and concluding that "counsel must tailor Dr. Galloway's expert testimony [at trial] to only his specific causation opinions . . . ."); *Frankum v. Boston Scientific Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *7 (S.D. W. Va. May 1, 2015) (excluding Dr. Sung's undisclosed general causation opinions); *see also In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-00738 (*Sholl v. Ethicon, Inc.*, Dkt. 132) (S.D. W. Va. Dec. 14, 2016) (excluding Dr. Carey's general-causation opinions); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-01148 (*Sacchetti v. Ethicon, Inc.*, Dkt. 106) (S.D. W. Va. Dec. 14, 2016) (same).

As such, this Court should exclude the general causation opinions offered in Dr. Wallach's Case-Specific Report. However, to the extent this Court does not exclude Dr. Wallach's general opinions entirely, they should be limited as set forth below.

B. General causation opinions regarding complications not experienced by Ms. Larson are irrelevant.

Even to the extent Dr. Wallach has been properly designated as a general expert by the Larson Plaintiffs, they would be the only Wave 13 plaintiffs to do so. Thus, Dr. Wallach's general causation opinions with no relation to the facts of Ms. Larson's case are irrelevant and not probative in the only case in which they could be offered.

Dr. Wallach offers general causation opinions in her Case-Specific Report regarding "mesh device-related complications" that she has "personally examined" in "over a hundred patients with mesh complications[,]" including opinions regarding complications not experienced by Ms. Larson. *See* Ex. D, Case-Specific Report at 3. Specific to Ms. Larson, Dr. Wallach opines that she has experienced mesh erosions, mesh bands, chronic pelvic pain[,] and dyspareunia caused by the Prolift. *Id.* at 30–31. Yet Dr. Wallach seeks to offer the general opinion that "mesh" devices generally are associated with complications such as fistula formation, infection of the mesh, bladder/vaginal/pelvic

infections caused by the mesh, nerve damage, pudendal neuralgia, and numerous other complications not experienced by Ms. Larson. *Id.* at 3.

This Court has consistently excluded evidence of complications not relevant to the plaintiff's complaints. *See, e.g.*, *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *5 (S.D. W. Va. Aug. 26, 2016) ("Evidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value."); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *8 (S.D. W. Va. Feb. 7, 2015) (excluding expert opinions relating to degradation where there was no evidence of degradation in any of the samples); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) (same); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 553 (S.D. W. Va. 2014) ("[T]he mention of cancer in the context of this case . . . would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value.") (internal quotation marks omitted)); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order (Dkt. 265) at 20 (S.D. W. Va. Nov. 20, 2014) ("Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value.").

Accordingly, Dr. Wallach's opinions and testimony regarding general causation matters and complications not experienced by Ms. Larson should be excluded.

II. The Court Should Exclude Dr. Wallach's Opinions Containing Legal Conclusions, Standards, and Legal Terms of Art, and Opinions Regarding Corporate Knowledge and Conduct.

Throughout her Case-Specific Report, Dr. Wallach offers various opinions regarding Corporate knowledge and conduct and opinions containing legal conclusions, using legal terms of art, and purporting to set forth applicable legal standards and duties. *See*, *e.g.* Ex. D, Case-Specific Report at 24 ("Ethicon failed to adequately warn" about "known problems" with Prolift); *id.* at (opining that the "Prolift IFU failed to warn" about various risks); *id.* at 25 ("If a medical device manufacturer knows" certain information regarding risks associated with product, "then it is misleading and

inadequate for that manufacturer not to disclose this."); and *id.* at 26–27 ("The design of the Prolift products is defective" and "Ethicon should have known" about certain alleged risks).

This Court has repeatedly held that it will not permit expert testimony on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because these matters "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *5–6, 15, 21 (S.D. W. Va. Jan. 15, 2014); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *4 (S.D. W. Va. Feb. 7, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Nor is a narrative history of a product's development proper expert testimony. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 646.

This Court has also repeatedly held that experts may not provide opinion testimony that states a legal standard, uses a legal term of art, or draws a legal conclusion by applying law to the facts—e.g., "failed to adequately disclose," "failed to warn on its label," "defective," "unreasonably dangerous," "not reasonably safe," "reasonable and prudent medical device manufacturer." *See, e.g.*, *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *4 (S.D. W. Va. Aug. 30, 2016); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013); *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *3 (S.D. W. Va. Apr. 24, 2015); *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *21 (S.D. W. Va. Jan. 15, 2014).

Accordingly, this Court should exclude the opinions contained in Dr. Wallach's Case-Specific Report that amount to improper opinions regarding Ethicon's corporate knowledge and conduct, as well as her opinions containing legal conclusions, purporting to set forth legal standards, and using legal terms of art.

III. This Court Should Exclude Dr. Wallach's Opinions Regarding Ethicon's Warnings and Informed Consent.

Throughout Dr. Wallach's Case-Specific Report, she offers opinions regarding the adequacy of Ethicon's warnings for Prolift. *See generally*, Ex. D, Case-Specific Report. As an initial matter, Dr. Wallach's warnings opinions contain legal conclusions and repeatedly use legal terms of art and should be excluded for those reasons alone. This Court should exclude Dr. Wallach's warnings opinions for the additional reasons set forth below.

A. Dr. Wallach is not qualified to offer opinions regarding the adequacy of the product IFUs.

This Court has previously held that an expert, such as Dr. Wallach, who is not "an expert in the development of product warning labels[,]" must possess "additional expertise to offer expert testimony about what an IFU should or should not include." *In re: Ethicon, Inc.*, MDL No. 2327, 2016 WL 4961675, at *3 (S.D. W. Va. Aug. 25, 2016). This Court has required more than experience reviewing IFUs in practice to qualify a doctor as a warnings expert. *Compare In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013) (finding doctor with "stellar qualifications as a urogynecologist" unqualified to opine on the adequacy of an IFU) *with Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703–04 (S.D. W. Va. 2014) (finding that urogynecologist who had consulted with a manufacturer on the development of an IFU was qualified to testify on the adequacy of warnings).

Nothing stated in her Case-Specific Report indicates that Dr. Wallach possesses the additional expertise required to offer opinions regarding the adequacy of Ethicon's warnings for Prolift. *See generally* Ex. D, Case-Specific Report. Rather, a review of her stated qualifications confirms that she is not qualified to offer such opinions. *Id.* at 1–3. She has never had a proctoring or consulting relationship with any mesh device manufacturer, with the exception of "consult[ing] with AMS approximately 7 years ago at a one day meeting[]" to "gather surgeon feedback on different meshes they had in development." *Id.* at 1–2. As such, Dr. Wallach has clearly never consulted with a medical

device manufacturer in connection with the development of product warnings. Her only "expertise in IFUs" is that she has "extensive clinical experience reviewing IFUs and consenting patients regarding IFUs." Ex. D, Case-Specific Report at 3.

Dr. Wallach is not qualified to offer opinions regarding the adequacy of the Prolift IFU and, as such, her warnings opinions should be excluded.

B. Dr. Wallach's opinions regarding the informed consent process are irrelevant and contain improper state-of-mind opinions.

Dr. Wallach also opines that "[f]ailure to provide physicians with relevant information bearing on the potential safety of a product that is known to the manufacturer prevents physicians from making informed decisions about whether to utilize the product. This failure also prevents physicians from properly counseling patients in considering whether to consent to the implantation of the medical device in their body." Ex. D, Case-Specific Report at 25.

This Court has consistently excluded testimony regarding "what [other] physicians know or should know about specified topics," recognizing that the jury is capable of listening to an implanting physician's testimony and reaching its own conclusions about the state of the physician's knowledge at the time she was making the prescribing decision. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493457, at *3 (S.D. W. Va. Aug. 25, 2016); *see also* Mem. Op. & Order, Doc. No. 119, *Guinn v. Ethicon, Inc.*, No. 2:12-cv-01121 (S.D. W. Va. Feb. 3, 2017) (excluding Dr. Rosenzweig's opinion that the implanting surgeon was unaware of the risks of vaginal mesh implants because "he cannot testify as to what someone did or did not know").[1] Thus, Dr. Wallach should be precluded from opining about

[1] *See also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding testimony about knowledge and state of mind because they are not appropriate subjects of expert testimony and will not assist the jury); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 564 (S.D. W. Va. 2014) (noting that "[t]he reasonableness of conduct and a party's then-existing state of mind 'are the sort of questions that lay

In addition, the adequacy of the informed consent process is irrelevant to failure-to-warn claims. "[T]he predicate of a claim for informed consent addresses the duty of the physician, not the manufacturer, to the patient." *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543 (3d Cir. 1994). Whether or not the informed consent process was adequate is not at issue in the only case for which Dr. Wallach may have been designated as a general expert; instead, under the learned intermediary doctrine, the only relevant issue is whether the warnings provided by Ethicon to the implanting physician were adequate.

Accordingly, the Court should preclude Dr. Wallach from offering any opinions about the adequacy of Ethicon's warnings for Prolift, as well as opinions regarding the informed consent process.

IV. This Court Should Limit Dr. Wallach's Opinions Regarding Safer Alternative Treatments and Procedures.

Dr. Wallach opines that "safer alternatives—including nonsurgical and surgical treatment options could have been chosen for Ms. Larson," if she and her physician had "been adequately warned" of the "problems" with Prolift. *See* Ex. D, Case-Specific Report at 31. Regarding alternative surgical options, Dr. Wallach opines, without explanation or justification, that a native tissue prolapse repair, a prolapse repair utilizing biologic grafts rather than synthetic mesh, or an abdominal sacrocolpopexy utilizing mesh are all "safer surgical interventions[.]" *Id.*

First, Dr. Wallach's opinion regarding "safer alternatives" to Prolift device should be excluded because Dr. Wallach does not cite a single study or reliable basis for such opinion. *See*, Ex. D, Case-Specific Report at 31. A mere conclusory statement that certain non-surgical treatments and non-mesh procedures are safer alternatives does not satisfy any of the factors considered to determine the

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jurors have been answering without expert assistance from time immemorial'") (quoting *Kidder, Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998)).

reliability of proffered expert testimony. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). As such, Dr. Wallach's "safer alternatives" opinions and testimony should be excluded as unreliable.

Second, Dr. Wallach should be precluded from offering any opinion that certain non-surgical and non-mesh procedures constitute safer alternatives to the Prolift product. This Court has recently excluded testimony offered by plaintiffs' experts who opine that alternative non-mesh procedures constitute safer alternatives, specifically holding that alternative non-mesh surgical procedures "do not inform the issue of whether an alternative design for a product exists." *In re: Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*, 2:12-md-02327, Memorandum Opinion and Order at 6 (S.D. W. Va. March 29, 2017); *see also Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, Memorandum Opinion and Order, at 3-4 (S.D. W.Va. Feb. 23, 2017) (emphasis added) ("Whether an alternative procedure could have been performed without the use of TVT **does nothing to inform the jury on the issue of an alternative, feasible design for the TVT**.") (emphasis added). "In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices . . . other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that cause the plaintiff's injuries." *Id.* (citing *Talley*, 179 F.3d at 162).

Dr. Wallach's opinions that certain non-surgical treatments and non-mesh procedures are safer alternatives to the Prolift are not helpful to the jury and should be excluded.

V. Dr. Wallach Should Be Precluded from Opining on the Competence of Other Physicians.

In her Case-Specific Report, Dr. Wallach offers several opinions bearing on the competence of other physicians, including that "[i]n the hands of many gynecological and urological surgeons, the blind passage of the metal trocars done during the implantation is unreasonably dangerous," and that "[e]ven to remove portions of the [Prolift] necessitates invasive surgery that few surgeons are qualified to perform." Ex. D, Case-Specific Report at 26.

As this Court has repeatedly observed, "[t]estimony regarding the competence of other physicians will not assist the jury" and is therefore irrelevant. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 723 (S.D. W. Va. 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014). Accordingly, this Court should preclude Dr. Wallach from offering opinions based on the competence of other physicians.

CONCLUSION

For the reasons stated above, the Court should grant Ethicon's Motion and preclude Plaintiffs' expert, Stacey Wallach, M.D., from offering the general opinions and testimony at issue herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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